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IN THE

Supreme Court of the United States

OCTOBER TERM, 1948.

No. 13

UNITED STATES OF AMERICA,
Petitioner,

vs.

RED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS, FIFTH CIRCUIT.

BRIEF FOR THE RESPONDENT.

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THE BUNTHORP-WARREN PRINTING COMPANY, 310 WEST JACKSON, CHICAGO

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OPINION BELOW.

The opinion of the Circuit Court of Appeals (R. 179-183) is reported at 164 F. 2d 245.

JURISDICTION.

The judgment of the Circuit Court of Appeals was entered on November 7, 1947 (R. 183). The petition for a writ of certiorari was filed February 6, 1948, and was granted April 19, 1948 (R. 185). The jurisdiction of this Court was invoked by petition under Section 240(a) of the Judicial Code as amended.

STATEMENT OF THE CASE.

Petitioner, the United States of America, filed a libel for condemnation in the United States District Court, Southern District of Ohio, alleging that the therapeutic devices sought to be condemned were misbranded when introduced into and while said devices were in interstate commerce (R. 1).

Dr. Fred Urbuteit of Tampa, Florida, filed a claim for a number of the devices (R. 5) and the case was transferred to the Northern District of Florida (R. 8).

The libel was amended (R. 11) and answered (R. 10), and the case tried without a jury (R. 15).

The issues framed by the pleadings in the lower court were whether or not the leaflet alleged to be a "labeling" of the devices, did in fact constitute a labeling under the Federal Food, Drug, and Cosmetic Act; and whether or not the statements in the alleged labeling are false and misleading.

The District Judge excluded evidence offered by the claimant Urbuteit (R. 159-163) and found for the libellant on those issues (R. 163). A decree of condemnation was entered (R. 168) and a motion for a new trial was filed by claimant (R. 169), but no brief or oral argument on the motion was permitted by the District Judge who promptly entered an order denying the motion (R. 170). From this order and the decree of condemnation the claimant Urbuteit appealed (R. 174).

The Circuit Court of Appeals reversed the District Court, and for a fair and concise further statement of the case the Court is requested to read the opinion of the Circuit Court of Appeals (R. 179-183).

A summary of the testimony in the District Court follows:

SUMMARY OF TESTIMONY.

Libellant's Witnesses:

Sidney Weissenberg (R. 16-23) testified that as an inspector for the United States Food and Drug Administration he inspected the devices proceeded against on the premises of Dr. J. J. H. Kelsch in Cincinnati, Ohio, making three visits—August 22, Sept. 5 and Sept. 28, 1945. On Sept. 5, 1945, he found four copies of a leaflet called "The Road to Health". Two copies were on Dr. Kelsch's desk and two were in his desk drawer.

O. O. Rowland (R. 23-35), trace clerk for the Railway Express Agency, produced shipping records showing shipments from Tampa, Florida, by Dr. Urbuteit or his agent to Dr. Kelsch in Cincinnati, Ohio, on the following dates: July 25, 1945; August 14, 1945; August 18, 1945; September 21, 1945. Appellant admits that these shipping dates are correct and represent the shipment of Sinuothermic devices to Dr. Kelsch. No leaflets were contained in these shipments, however, and no claim that they were has been made by the Government.

Dr. J. J. H. Kelsch (R. 25-35) testified that he is a Chiropractor and Naturopath practicing in Cincinnati, Ohio; that he went to Tampa and received instruction from Dr. Urbuteit in the use of the Sinuothermic Device, arranged for the purchase of some and rental of other of the devices, and a supply of the leaflets, "The Road to Health" and later received the devices in Cincinnati. After the devices had been received he received a bulk shipment of the leaflets—he could not remember when except that it was sometime around September. He mailed out the leaflets to his patients and used the devices in his practice. On direct examination he described very briefly the general manner in which the device is used but was not per-

mitted to testify as to the result obtained when asked that question on cross-examination. He testified that he received the devices as a practicing physician for use in his practice and not as a seller or vendor of therapeutic devices but that he sold one to a family who took treatments from him but who lived in Kentucky, and wanted one so their treatments could be continued at their home.

Mrs. Joseph H. Kelsch (R. 35-36) testified simply to the fact that she signed the express records previously introduced and received the devices which were later seized.

W. C. Osterbrock, (R. 36-49) professor of Electrical Engineering at Ohio State University testified that he had examined the devices and described their construction. The substance of his testimony was that the devices by means of a potentiometer and a transformer reduced the current from the standard electric 115 volt A. C. lighting circuit—that there are many and varied forms of transformers and that from his examination he could not tell how the transformer in the device was wound and constructed. Condition of the skin, moisture, pressure and other factors vary the resistance of the human body to the passage of an electrical current. Volt and ampere meters (some of the devices having such meters) are not accurate in the lower 20% of their full scale reading. His tests or examination of the device was limited to a measurement of the current by his laboratory meters and a device known as an oscillograph which shows the wave form of the current.

Daniel R. McMillan, Jr., (R. 49-53) Professor of Physics at Emory University testified briefly, there being nothing in his testimony that was not included by Professor Osterbrock.

John Haldi, (R. 53-70) Professor of Physiology at Emory University testified rather extensively and willingly about himself and his experiments. He managed to kill several

dogs by fastening the electrodes of the device to them and giving them a heavy load of electrical energy. He found that when he first turned on the current their respiration and blood pressure was affected and that it then returned to normal. He was afraid to try it on human beings other than to simply have them hold the electrodes and feel a slight tingle. He did not see how electrical energy could bring about any physiological changes in the human body or how a condition could be judged by the resistance to a current.

Seven doctors of medicine came to the witness stand one after the other (R. 70-115). None of them except one had ever so much as seen the device before he came to court. None of them were shown to be specialists in any form of electrotherapy, except that one of them is a Roentgenologist, confining his practice to the use of the X-ray. They all admitted that they knew nothing about the device but all were quite sure it was no good. One of them told of two experiments made by him with the device—one on an advanced tubercular patient and the other on a cancerous leg. The nature of his superficial tests as disclosed by his testimony and his testimony relative thereto cannot be fully appreciated without a reading of that portion of the record. (R. 113-115.)

Claimant's Witnesses:

As the first witness for the Claimant Mr. James C. Pearson, (R. 117-119) Chief Inspector of the Atlanta Station of the Food and Drug Administration, was called for the purpose of showing that his men had interviewed large numbers of patients of Dr. Urbuteit and had investigated the result of their treatments with the Sinuothermic device and that Dr. Urbuteit, in the office of the Pure Food and Drug Administration in Atlanta had offered full cooperation and requested the cooperation and participa-

tion of the Administration in making complete and thorough clinical tests of the Sinuothermic device. On the objection of Libellant's attorneys that such testimony would be irrelevant the Court did not require Mr. Pearson to answer the questions.

Dr. Fred Urbuteit, Claimant, (R. 119-158) testified as to his education and training and practice as a Naturopathic Physician, and his experiments over many years in an effort to find a form of electrical energy that would amplify the function of the various parts of the human body. During the course of his experiments and search he developed a serious arthritic condition and while in its last stages with his body highly sensitized he was able to feel the direct waves from the instrument without any application of pads or any sort of contact with his body, and with the aid of an associate working under his direction he was able to make changes in it until the effect of the wave on his body was soothing rather than coarse and irritating. From this point the part of the instrument necessary to pick up the wave or energy and apply or direct it to any particular part of the body in the necessary volume was developed. The instrument went through various stages of mechanical construction, its volume being controlled mechanically before potentiometers were made, until its present mechanical form was developed. He described his own physical condition and the results obtained from his treatments of himself with the device and described his examination and treatment of each of the persons mentioned in the leaflet "The Road to Health", the statements in which were by the Libellant alleged to be false and misleading, and stated that each of the statements therein was true.

Dr. Urbuteit described the way the Sinuothermic device is used in the diagnosis of the condition of and the treatment of abnormal conditions in the human body.

This general description is in addition to his statements describing the specific cases mentioned in the leaflet and appears at pages 126-130 of the record. He stated that he used various accepted methods of diagnosis in addition to the Sinuothermic device but that he had found after long experience that when the Sinuothermic device located where something was wrong, the chemical or other tests that might be necessary to determine the name of the ailment would not be necessary to the treatment and the patient getting well. He stated that he estimated the number of people treated by him with the device to be about ten thousand and had in the Court room a trunk containing thousands of cards, each of which was the record of his diagnosis and treatment of a different patient; that no person had ever suffered any injury or adverse effect from the device.

After the general examination of Dr. Urbuteit his attorney, the writer of this brief, stated that he proposed to interrogate Dr. Urbuteit as to his diagnosis and treatment of a number of witnesses present and then interrogate those witnesses as to their condition as known to them and their treatment by Dr. Urbuteit with the Sinuothermic device.

On objection of the attorney for Libellant the Court refused to permit Dr. Urbuteit to testify as to his diagnosis of Mrs. J. W. Porter (R. 158-159).

Mrs. J. W. Porter was then called as a witness and stated that she took treatments from Dr. Urbuteit with the Sinuothermic device about nine years before. On objection of Libellant's attorney the Court refused to permit her to testify as to her condition as known to her (R. 159-161).

Proffer of the testimony of approximately thirty witnesses as to their treatment by Dr. Urbuteit with the Sinuothermic device and their condition as known to them be-

fore, during and after the treatment was then made by Claimant's attorney, together with a proffer of testimony by Dr. Urbuteit as to his diagnosis of the condition of such witnesses with the use of the Sinuothermic device and otherwise, his treatment of such witnesses with the Sinuothermic device and the results obtained from such treatments. On objection of Libellant's attorney the Court refused the proffer (R. 162-163).

The Court then, without hearing any argument or summary and without himself making any summary or explanation, stated that "The Court finds for the Government. The United States Attorneys will prepare an appropriate decree and present the same to the Court" (R. 163).

SPECIFICATION OF ERRORS.

The Petitioner (the United States) reluctantly admits that the Circuit Court of Appeals was correct in holding the District Court in error for excluding testimony proffered by Claimant (Urbuteit, the Respondent here), but tries to claim that the excluded testimony would not refer to use of the Sinuothermic device in diagnosis and that there was substantial evidence to support a decree of condemnation for misbranding as regards the diagnostic use of the device, and that the Circuit Court of Appeals erred in not so holding.

The principal alleged error that Petitioner seems to urge, however, is the holding by the Circuit Court of Appeals that the leaflets the Petitioner calls "labeling" did not accompany the devices in interstate commerce and, therefore, did not constitute "labeling"—and the expression of doubt by the Court that the leaflets were in their nature "labeling" even if they had accompanied the devices in interstate commerce.

ARGUMENT.

SUMMARY: As to the first of the above stated alleged errors Respondent maintains that there was no substantial evidence to sustain a finding that there was a misbranding as regards the diagnostic use of the device—regardless of whether or not the leaflets actually constituted labeling—and further maintains that the excluded testimony would have dealt definitely and extensively with the use of the device in diagnosis and the results obtained.

As to the second of the alleged errors, it is the contention of Respondent that the leaflets were never in interstate commerce at the same time the devices were—and not even the Petitioner claims that they were—and for this reason they did not accompany the devices and consequently were not labeling of the devices when introduced into or while in interstate commerce. It is the further contention of Respondent that it is clear from a reading of the leaflet that it is not in its nature a labeling of the devices and would not have been labeling if the leaflets had been packed in the boxes with the devices.

No Misrepresentations as to the Diagnostic Capacity of the "Sinuothermic" Device Were Admitted or Established as Contended by Petitioner.

Petitioner has quoted isolated excerpts from the leaflet and testimony in an effort to show that the leaflet contained false statements as to the value or use of the Sinuothermic device in diagnosis.

The testimony has already been summarized in this brief and by reference to that summary or the complete transcript in the record the Court will see that the evidence introduced to support the allegations of falsity was

composed entirely of the opinions of doctors who were qualified simply as doctors and not experts or specialists in the field of electrotherapy. Each and every one of them admitted that he did not know anything about the Sinuothermic device. Their opinion was based solely on the fact that they simply had no knowledge of any electrical device that would be effective as claimed. The writer of this brief is a lawyer licensed to practice in the State of Florida. He has never practiced in any other state. If asked a question about some point of law in another state he might feel fairly sure that it was so and so because he knew nothing to the contrary, but his opinion on the point would not be worth anything and he would not have the gall to hold himself out as qualified to answer the question. The witnesses in this case, however, were not bothered by such an inferiority complex.

The Food and Drug Administration was, by the answer or claim of Dr. Urbuteit filed in this case (R. 7) offered co-operation and invited to make thorough clinical tests of the Sinuothermic device. This writer personally called on the head of that agency in Washington and urged such tests, but to no avail. The flimsy evidence offered, therefore, was by choice and not necessity.

As against this sort of testimony Dr. Urbuteit told of developing the device, how it works, of his many years of practice with it and the results obtained in both diagnosis and treatment. He went through the leaflet from one end to the other and told of each case or incident related therein, stated who the people were and swore that the statements were true. A number of those people and many others were waiting outside the Court room to give factual testimony to support his statements. The Food and Drug Administration had interviewed most of those people and many others who had taken Sinuothermic treatments. The Administration knew to what other

doctors many of those people had been—but chose to rely on the testimony of a group of doctors whose opinions, or whose testimony at least, would not in any way be based on experience or knowledge of specific cases.

Petitioner, in contending that it would be entitled to a decree of condemnation IF the leaflets were labeling and IF they accompanied the devices and IF the statements in the leaflets contained false representations as to the therapeutic value of the device, plants its contention on a false premise—that the evidence which the Circuit Court of Appeals held was improperly excluded by the District Court did not relate to the diagnostic capacity of the machines. Now the nature of the evidence excluded can be learned from one place only and that is the proffer, objections to which the District Court sustained. (R. 162.) In that proffer it was plainly stated that Claimant offers to testify as to his diagnosis with the use of the Sinuothermic machine and otherwise * * *, so it is readily apparent that the contention of Petitioner is nothing but wishful thinking.

In this connection it might be interesting to take note of that word "diagnosis". 12 *Words and Phrases* 375 refers us to a couple of cases that state rules or principles that any person of average intelligence and experience is familiar with. "At the best, diagnosis is little more than a guess enlightened by experience"—*Swan* v. *Long Island R. Co.*, 29 NYS 337; and "A practitioner has diagnosed a case when he makes such examination of the patient as he regards as sufficient to indicate to him the cause of the trouble and its proper treatment", *People* v. *Zinke*, 7 NYS 2d 941. Every member of the Court probably knows of a number of people who have gone from one doctor to another and gotten a different diagnosis each time. Appellant submits that the best proof of the accuracy of any system or means of diagnosis and the

effectiveness of any treatment is the record of repetitive cases in which the diagnosis is made, the treatment is administered and the patient gets well. That is the evidence that the Court would not admit simply because several doctors of another faith had no experience with or knowledge of a device used by the doctor testifying in his diagnosis and treatment and did not believe it would be effective for diagnosis.

The effort of Petitioner to attribute to the word "diagnosis", and statements concerning diagnosis, meanings and imputations that no sensible person would ever seriously think of, would be laughable if not involved in such a serious matter. There are many mechanical instrumentalities used in diagnosis by the several branches of the healing art, and some of them do remarkable things, but they are useless without the human personality and the trained mind that can draw conclusions from the factors indicated. As simple a thing as an electric meter "registers exactly"—but how many people who pay electric bills can tell just what it registers or what it means. It's simply an aid to the electric company in making its diagnosis of the customer's liability, and a human mind is required to read the meter and calculate the liability. We say that we were examined or our case was diagnosed by or with an X-ray, or an electro-cardiograph or something else, and that the X-ray showed so and so or the electro-cardiograph reading showed such and such a condition, but we don't mean to intimate that anything was done without the intervention of a trained mind and no one would think of attributing any such meaning to our statement.

The Leaflets Did Not "Accompany" the Devices so as to Constitute "Labeling".

The present litigation began with the filing of a libel under the provisions of the Federal Food, Drug, and Cosmetic Act—specifically:

> Sec. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. * * *

Working backwards in an analysis of the situation we find that the devices were found within the jurisdiction of the District Court where the libel was filed AFTER they had been in interstate commerce and were in use in a doctor's office. So far so good—but were they "misbranded WHEN INTRODUCED INTO or WHILE IN INTERSTATE COMMERCE"?

> Sec. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

For the sake of argument we will assume that the leaflets contained false or misleading statements. But were the leaflets "labeling"?

> Sec. 201. For the purposes of this Act—* * * (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The leaflets complained of were not "upon" the devices "or any of its containers or wrappers". Now did the leaflets "accompany" the devices? It might be said that the leaflets and the devices were accompanying each other

in the doctor's office in Ohio. Six of the leaflets were found in his suite of offices and the devices were also in his suite of offices. Two of the leaflets were on the doctor's desk and four in it. The devices were in other rooms (R. 20). They were accompanying each other just like two patients who came in at different times and were in different rooms. But that was AFTER the devices had passed out of interstate commerce, so we will say for the sake of argument that the devices were misbranded AFTER SHIPMENT IN INTERSTATE COMMERCE. Now that might have been a crime under

> Sec. 301. The following acts and the causing thereof are hereby prohibited:
>
> * * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

if the devices were being held for sale (which they were not) but such a violation as that would not be a basis for a libel—and this was a libel and not a prosecution.

We back on up further and we find from the undisputed evidence of Petitioner's own witnesses that the devices and the leaflets were shipped at different times by different mediums of transportation, arrived at different times and were not even in interstate commerce simultaneously at any given moment. Now the leaflets could not be "labeling" except while "accompanying" the devices, and the devices would not be subject to libel unless misbranded "when introduced into or while in interstate commerce", so to sustain its libel Petitioner must show that the leaflets accompanied the devices "when (the devices) introduced into or while in interstate commerce". The evidence is absolutely to the contrary. Now that ought to end the matter and

require a dismissal of the libel—and that's what the Circuit Court of Appeals thought.

When confronted with the opinion of the Circuit Court of Appeals, however, the administrators of the Act just couldn't bear to have their wings clipped so they would have to stay within the bounds Congress prescribed for them. As a last resort they turned to spiritualism—went into a trance—and were finally able to see the ethereal forms of the devices and the leaflets floating on a cloud in the spirit world, accompanying each other in spirit—in a "textual relationship" if you please. All we need now is for the Interstate Commerce Commission to go into a trance and take jurisdiction over the spiritual means of transportation so we can call it interstate commerce.

The idea that the jurisdictional factor of printed matter "accompanying devices when introduced into or while in interstate commerce" is present when they were never even in interstate commerce at the same time, is utterly ridiculous.

Words are but the tools of men. Skilled artisans choose their tools carefully and use them rightly for the purpose they were made. The careless or ignorant often misuse a tool, dulling it and damaging that on which they use it. So it is with words. The Congress used perfectly clear and plain language in the statutory provisions under discussion in this case, and it requires the worst kind of distortion to eliminate physical contiguity from the necessary connotation of the word "accompanying," and to substitute therefor some spiritual relationship. If the Congress had intended for the libel provision of the statute to apply to shipments misbranded AFTER shipment in interstate commerce it would have said so—just as it provided Sec. 301(k) to make misbranding punishable if done while an article was held for sale after interstate shipment.

The Leaflets Were Not in Their Nature Labeling of the Devices.

The opinion of the Circuit Court of Appeals (R. 181, second paragraph) discusses the nature of the leaflet. The question is a very practical one—a question of fact to be determined by good common sense. The Circuit Court of Appeals has so approached it—and although it was not necessary for the Court to decide whether or not the leaflets were in their nature labeling—the Court expressed its serious doubt that they were.

The leaflets are an advertisement of an institution where personal and professional services are offered for sale in treatment of the sick and in training or teaching. The Sinuothermic device is mentioned as an instrumentality used in the institution but such mention is incidental to the advertisement of the services offered. Dr. Kelsch, Respondent's witness, testified that he got the leaflets to mail out to his patients and that he did so (R. 30). Respondent introduced in evidence a printed form letter on the letterhead of Sinuothermic Institute, Inc., and signed by Dr. Urbuteit, addressed to Dear Patient. This letter does not appear in the record but its identification and the statement that it was obtained from Dr. Kelsch appears (R. 19). The letter was mailed by Dr. Kelsch with the leaflets to his patients and is a message from Dr. Urbuteit to the patient stating that Dr. Kelsch has taken a course in Sinuothermic and is prepared to "carry on this advanced scientific work in his own office". There is no mention whatever of any kind of device or equipment. This letter illustrates the purpose and inherent nature of the leaflets and makes perfectly clear the fact that they are an advertisement of a professional service and not an advertisement of a device—much less a labeling of a device.

Conclusion.

The Circuit Court of Appeals wrote a sound and sensible opinion and supported it with logical reasoning. For the reasons stated in the opinion itself and the further reasons herein stated that opinion should stand and the judgment of the Circuit Court of Appeals should be affirmed.

Respectfully submitted,

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October, 1948.